No. 01-660 (3)

Supreme Court, U.S.
FILED
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In The

# Supreme Court of the United States

ELI LILLY AND COMPANY,

*Petitioner,*

v.

BARR LABORATORIES, INC., and APOTEX, INC., and BERNARD C. SHERMAN, and GENEVA PHARMACEUTICALS, INC., and INTERPHARM, INC.,

*Respondents.*

**On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit**

## BRIEF OF INTELLECTUAL PROPERTY LAW PROFESSORS AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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Dated: December 11, 2001

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25 pp

## QUESTIONS PRESENTED

1. Did the Court of Appeals err in invalidating Petitioner's basic patent on the antidepressant drug Prozac on the ground that the 1974 discovery claimed by the patent was "obvious" when compared to a second patented discovery that was not even made until 1983, years after the 1974 discovery was first publicly disclosed as "prior art"?

2. Did the Court of Appeals err in ruling that Petitioner was not entitled, despite the plain language of 35 U.S.C. § 253 and uniform precedents applying it, to preserve the validity of its basic Prozac patent by "disclaiming" the final seven months of its patent term held by the court to be an "unjustified timewise extension" of patent exclusivity?

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## BRIEF OF INTELLECTUAL PROPERTY LAW PROFESSORS AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

*Amici Curiae* Robert Brauneis, Mark D. Janis, Jay P. Kesan, Mark Lemley and John R. Thomas (collectively "Intellectual Property Law Professors") respectfully submit this brief in support of petitioner, Eli Lilly and Company ("Lilly"), encouraging the grant of a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.[1]

## INTEREST OF *AMICI CURIAE*

*Amici* are law professors who teach and write about intellectual property law at law schools within the United States. *Amici* are concerned about the continued role of the patent law in stimulating innovation, avoiding the duplicative efforts associated with rivalrous research and development efforts, and forming markets in technological products and processes.

At first glance, the Federal Circuit's decision in this case may appear to involve a narrow technical issue that does not merit this Court's attention. *Amici* are convinced, however, that the decision below undercuts several fundamental principles underlying the patent

[1] Pursuant to this Court's Rule 37.2(a), letters of consent from all parties to the filing of this brief have been filed with the clerk. Pursuant to this Court's Rule 37.6, *amici* represent that this brief was not authored in whole or in part by counsel for any party, and that no person or entity other than *amici* made a monetary contribution to the preparation or submission of this brief.

system. The decision causes serious damage to the basic principle that inventors should be able to patent an improvement to their own patented inventions on as favorable a basis as others, and thus deters inventors from continuing to innovate in the field in which they are best equipped to do so. The decision also damages the longstanding principle that newly discovered medical applications of a known compound may be independently patentable, and thus particularly threatens the heavily patent-dependent pharmaceutical and biotechnology industries. Finally, the decision erodes the statutory presumption of validity for issued patents, by requiring that holders of multiple related patents prove that they solicited their patents with all possible speed.

*Amici* submit this brief to apprise this Court of the importance of the questions presented in this case to fundamental principles underlying the principal mechanism for encouraging technological innovation in the United States. *Amici* urge this Court to grant the petition for certiorari in this case to clarify and reinforce these basic principles of patent law.

## SUMMARY OF REASONS FOR GRANTING THE PETITION

The Federal Circuit's decision in this case unwisely elevates the doctrine of "double patenting" from a limited judicial cure of a specific problem to a sweeping basis for striking down patents on improvement inventions. In conflict with patent laws and policies of long application, the decision discourages innovators from refining, advancing and otherwise improving upon their

inventions. The decision will also weigh heavily against patents on pharmaceuticals, biotechnologies and other inventions with biological properties, for it announces a far-reaching doctrine that will block the issuance of patents claiming novel and nonobvious medical uses for known compounds. In conflict with the provisions of the Patent Act and sound patent administration policies, the Court of Appeals has also saddled patentees with the burden of demonstrating that they expeditiously procured their patents.

The Federal Circuit's decision thus implicates fundamental issues in United States patent law, and undermines several basic patent law principles. Because the Federal Circuit has exclusive appellate jurisdiction over patent cases,[2] its decision will weaken innovation policy nationwide unless this Court exercises its power of review. For these reasons, the Court should grant *certiorari* in this case.

## REASONS FOR GRANTING THE PETITION

### I. The Federal Circuit's Unwarranted Extension of the "Double Patenting" Doctrine Undermines the Fundamental Patent Law Policy of Encouraging Cumulative Innovation.

Technological advance often occurs through incremental developments. Many fields experience cumulative technological advances, in that the sense that today's advances build upon and interface with other features of

[2] 28 U.S.C. § 1295(a) (2000).

existing technology.[3] This pattern of follow-on invention occurs in many significant U.S. industries, ranging from automobiles to semiconductors and computers.[4] In fields such as pharmaceuticals, this pattern of follow-on invention is observed when inventors discover new medical indications for compounds already within the state of the art.

The Patent Act expressly provides that improvement inventions can be independently patented, provided that these inventions are novel and nonobvious.[5] The separate patentability of improvement inventions has traditionally provided important incentives for individuals and enterprises to continue to advance and refine existing technologies.[6] As explained by the late Judge Giles S. Rich:

> The patent system is an incentive system calculated to do two things, principally. First, it stimulates work, research, development, invention, and discovery by holding out the prospect of profit. Second, in exchange for and as a condition of the patent protection, it secures a full disclosure of the invention. Promotion of the useful arts takes place through the combination of these two factors, the doing of the work and the disclosure of the results thereof. In the very nature of things, progress is made as the result

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[3] *See* Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 (1990).

[4] *See* RICHARD R. NELSON & STANLEY G. WINTER, AN EVOLUTIONARY THEORY OF ECONOMIC CHANGE (1982); DEVENDRA SAHAL, PATTERNS OF TECHNOLOGICAL INNOVATION (1981).

[5] 35 U.S.C. § 101 (2000).

[6] *See* Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEXAS L. REV. 989 (1997).

> of both the big and the little contributions, mostly the latter. We get a telephone or a triode – in modern jargon a 'major scientific breakthrough' – only at rare intervals. The seemingly little advances are the bread and butter of progress and sometimes turn out to be of much greater importance than at first thought. The biggest contribution the patent system makes to progress is to induce a steady flow of contributions and to secure their continuous disclosure.[7]

A sound patent system should offer incentives to improve upon basic innovations not only to the patentee's competitors, but to the original inventor as well. Having researched and developed a basic technology, the original innovator often stands in the best position to further perfect the invention. The separate patentability of improvement inventions stimulates inventors to procure patent protection of basic inventions as well. Otherwise, such inventors would justly be concerned that a patent on a fundamental invention might limit their prospects for obtaining patents upon new and nonobvious improvements.

The Federal Circuit's decision in the instant case undermines these established principles. That decision the Federal Circuit struck down U.S. Patent No. 4,626,549 (the "Molloy patent"), Lilly's basic patent concerning fluoxetine hydrochloride. The basis for invalidity was an improvement patent, U.S. Patent No. 4,590,213 (the "Stark patent"), that Lilly had applied for nine years after it filed the Molloy patent application. The Federal Circuit concluded that Lilly had engaged in impermissible double

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[7] *In re Nelson*, 280 F.2d 172, 182 (C.C.P.A. 1960).

patenting and compelled Lilly to forfeit the ostensibly duplicative Molloy patent. The court's unprecedented application of the double patenting doctrine reached an unjust result under the facts of this case. Moreover, the court's extension of the double patenting doctrine holds deleterious consequences for the patent system's goal of sustaining incremental technological advance.

The double patenting doctrine has traditionally prevented an inventor from obtaining multiple patents on inventions that are identical or are obvious variants of one another.[8] The obviousness-type double patenting doctrine is a judicial creation that lacks an expression in the Patent Act. The need for a double patenting doctrine arises because, with the exception of the statutory bars of paragraphs (b) and (d) of 35 U.S.C. § 102, the statutory definition of the prior art generally does not include the inventor's own earlier work.[9] As a result, an inventor's earlier patent applications are ordinarily not considered when an assessment is made whether or not the invention meets the patentability requirements of novelty and non-obviousness.[10]

Absent a double patenting doctrine, an inventor might abuse the patent acquisition process by filing multiple patent applications claiming the same or closely related inventions. Because these applications do not count as prior art against each other, the inventor could potentially obtain numerous patents over a period of

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[8] *See Miller v. Eagle Manufacturing Co.*, 151 U.S. 186 (1894).

[9] *See* 35 U.S.C. § 102 (2000).

[10] *See* 35 U.S.C. §§ 102, 103 (2000).

many years. This technique would allow an inventor effectively to extend the statutory patent term by procuring a series of overlapping patents. It would also expose competitors to suits on several patents rather than one.

Although the double patenting doctrine serves an important role in the patent law, it has not traditionally been applied to the circumstances at issue in this case. Double patenting has previously served as a discrete policing mechanism against the exploitation of a specific statutory loophole. The double patenting doctrine is unnecessary where one patent serves as prior art against another. In such cases, the statutory requirements of novelty and nonobviousness serve to assess whether the later invention presents a patentable advance over the earlier one.[11] As a result, courts and the PTO have applied double patenting principles only when one patent does not serve as prior art against the other.

In this case, Lilly filed the application that led to the Molloy patent on January 10, 1974. The application that led to the Stark patent was filed over nine years later, on April 8, 1983. The disclosure of the Molloy patent serves as prior art against the Stark patent.[12] In fact, the PTO expressly considered the Molloy patent when deciding that the Stark patent should issue. By allowing Stark's

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[11] *See In re Boylan*, 392 F.2d 1017, 1018 n.1 (C.C.P.A. 1968) ("in analyzing cases of these types, it must always be carefully observed that the appellant's patent is not 'prior art' under either section 102 or section 103 of the 1952 Patent Act (35 U.S.C., as amended).").

[12] *See* 35 U.S.C. § 102 (2000).

application to mature into an issued patent, the PTO already concluded that the invention claimed in the Stark patent presented a novel, nonobvious and patentable advance over the prior art. The PTO's decision is contestable, by accused infringers in a court,[13] or by any member of the public through reexamination proceedings at the PTO.[14] No sound explanation exists for further consideration of the relationship between the Stark and Molloy patents through a judicially crafted doctrine.

This novel application of the double patenting doctrine holds unusual and unjust consequences that were not previously known to the patent system. Prior to the Federal Circuit's decision in this case, the validity of two patents that each claimed new and nonobvious inventions over the prior art did not depend upon their ownership.[15] The Federal Circuit's ruling achieves the bizarre result of tying the validity of an improvement patent to the ownership of the basic patent. If a patent on an improvement is owned by the same entity as the patent on the basic technology, then the double patenting doctrine may defeat one of them even though both patents fully describe and clearly claimed patentable inventions. Yet if the identical patents were owned by different individuals, then their validity would be upheld.

The effect of the Federal Circuit holding is to discriminate among inventors in a manner that is unjust and

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[13] 35 U.S.C. § 282 (2000).

[14] 35 U.S.C. § 302 (2000).

[15] *See Thomson-Houston Electric Co. v. Ohio Brass Co.*, 80 F. 712, 727 (6th Cir. 1897).

economically harmful. Basic inventions may not yet be optimized for the marketplace. Further refinements may be needed, and the party best positioned to achieve these refinements may well be the original inventor. Regrettably, the new double patenting doctrine allows all but the pioneering inventor to obtain proprietary positions in both the original invention and subsequent advancements. Such a rule may discourage inventors from seeking out new uses for known compositions or otherwise optimizing their inventions. It tends to encourage pioneering inventors to employ counterproductive strategies of enterprise organization, so that pioneering and improvement technologies are developed by entities that are formally distinct. And it may also chill the research and development expenditures that lead to pioneering developments in the first place.

Double patenting is a complex doctrine that can be elusive to apply. In this case, the Court of Appeals failed to realize that it should not have employed the double patenting doctrine at all. In so doing, the Federal Circuit departed from precedent and created bad law. By granting *certiorari*, this Court can correct the Federal Circuit's error and prevent its broad-reaching negative consequences.

## II. The Federal Circuit's Decision Weighs Heavily Against Inventions with Biological Activity Properties, and Thus Broadly Impacts the Patent-Dependent Pharmaceutical and Biotechnology Industries.

In this case, the Court of Appeals concluded that a patent upon a new and nonobvious anxiety-treating use

of fluoxetine invalidated a patent on the earlier discovery of the serotonin blocking properties of fluoxetine. According to the Federal Circuit, because "the inherent biological function" and "natural result" of administration of fluoxetine hydrochloride is the inhibition of serotonin uptake, Molloy's earlier discovery was intrinsic to Stark's later one.[16] The court therefore invalidated the Molloy patent based upon the Stark patent.

This chain of reasoning was not only inappropriate in this case, but it holds wide-ranging consequences for the pharmaceutical and biotechnology industries. U.S. patent law has for many years recognized that patents may issue for new uses of known compositions of matter.[17] Long-standing precedent also recognizes that accidental, unappreciated prior use of an invention does not bar its subsequent patenting. Many decisions have reasoned that unappreciated events are, by definition, unknown to the public and thus not anticipatory.[18]

*Tilghman v. Proctor* was one such case.[19] There the patentee claimed "the manufacturing of fat acids and glycerine from fatty bodies by the action of water at a high temperature and pressure."[20] The accused infringers pointed to several alleged anticipations, ranging from a

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[16] *Eli Lilly and Co. v. Barr Laboratories, Inc.*, 251 F.3d 955, 969, 970 (Fed. Cir. 2000).

[17] *See* 35 U.S.C. § 101 (2000).

[18] *See* Bradord J. Duft & Eric P. Mirabel, *Principles of Inherency*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 539 (1995).

[19] 102 U.S. 707 (1880).

[20] 102 U.S. at 709.

water barometer, to a steam engine, to a method of purifying fats and oils preparatory to soap making. Although the patented method well have been previously performed in connection with these public domain technologies, such performances had not been understood. The Court concluded that these performances would not invalidate the later patent:

> If the acids were accidentally and unwittingly produced, whilst the operators were in pursuit of other and different results, without exciting attention and without its even being known what was done or how it had been done, it would be absurd to say that this was an anticipation of Tilghman's discovery.[21]

*Tilghman v. Proctor* and subsequent cases have articulated the general rule that an incidental or unknown duplication of an invention cannot constitute an anticipation.[22] The abrupt departure of the Court of Appeals from

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[21] 102 U.S. at 711-12.

[22] One decision of the Court of Customs and Patent Appeals, *Application of Marshall*, 578 F.2d 301 (C.C.P.A. 1978), appears particularly on point. There the applicant claimed a weight control process involving the use of the anesthetic oxethazaine. The PTO cited a prior art reference, the Physician's Desk Reference or PDR, that taught the use of oxethazaine in order to treat esophagitis, gastritis, peptic ulcer and irritable colon syndrome. In overturning the PTO's decision rejecting Marshall's application, the court concluded: "Nothing in the PDR remotely suggests taking oxethazaine to lose weight. If anyone ever lost weight by following the PDR teachings it was an unrecognized accident. An accidental or unwitting duplication of an invention cannot constitute an anticipation." 578 F.2d at 304.

both the terms of the Patent Act and this binding precedent is apparent from the court's methodology used to judge the novelty of the uses to which fluoxetine hydrochloride may be put. In articulating the biological properties of fluoxetine hydrochloride, the Federal Circuit cited no reference from the patent or scientific literature available prior to the filing of Molloy's patent application. Instead, the court exclusively cited documents published after the filing date of the Molloy application. The Patent Act simply does not allow the patentability of inventions to be judged by subsequent technical progress.[23] As observed by Judge Newman in her opinion dissenting from the Federal Circuit's refusal to consider the case *en banc*: "Later discoveries and scientific advances may well elucidate the earlier ones, but that does not retrospectively erase the patentability of the earlier work."[24]

The scope of the error in this case exceeds that of the faulty application of hindsight to a particular set of facts. Judge Newman perceptively observed that "every biological property is a natural and inherent result of the chemical structure from which it arises, whether or not it has been discovered."[25] Justice Frankfurter realized as much over fifty years ago, when he stated:

> Everything that happens may be deemed the "work of nature," and any patentable composite exemplifies in its properties "the laws of

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[23] *See, e.g.*, 35 U.S.C. § 103(a) (2000) (mandating that nonobviousness be judged "at the time the invention was made").

[24] 251 F.3d at 974.

[25] 251 F.3d at 955.

> nature." Arguments drawn from such terms for ascertaining patentability could fairly be employed to challenge almost every patent.[26]

The reasoning relied on by the court below will weigh heavily against inventions that exhibit biological properties. Many such inventions identify medical indications that were not understood to be associated with the chemical structure of a known compound. As a result, the *Eli Lilly* decision may act to the detriment of two industries, pharmaceuticals and biotechnology, that have the distinction of being both particularly dependent upon the patent system, and fields in which U.S. enterprises enjoy a competitive advantage.

Academic studies have repeatedly shown that enterprises within the pharmaceutical industry view patents as essential to developing and marketing innovations. The widely cited survey conducted by Yale University President Richard Levin and his research associates queried 650 U.S. R&D executives in order to evaluate the effectiveness of patents versus other methods of appropriating private returns. Of all U.S. industries considered by the study, pharmaceutical enterprises most heavily relied upon the presence of a patent system to appropriate returns on their investments.[27]

In 1985, a survey led by former University of Pennsylvania Professor Edwin Mansfield asked chief R&D

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[26] *Funk Brothers Seed Co. v. Kalo Innoculant Co.*, 333 U.S. 127 (1948) (Frankfurther, J., concurring).

[27] RICHARD LEVIN, ET AL., APPROPRIATING THE RETURNS FROM INDUSTRIAL RESEARCH AND DEVELOPMENT, BROOKINGS PAPERS ON ECONOMIC ACTIVITY, No. 3, 783 (1987).

executives of 100 U.S. firms what proportion of the inventions they developed between 1981 and 1983 would not have been developed without patent protection. Pharmaceuticals again displayed strong dependence on patent protection. Survey respondents claimed that 60 percent of their drugs would not have been developed without patents. Further, the respondents stated that 65 percent of the drugs would not have been commercially introduced absent patent protection.[28]

The biotechnology industry also appears to rely upon a robust patent law in order to secure capitalization. Reaction to the recent joint statement of U.S. President Bill Clinton and U.K. Prime Minister Tony Blair suggests that investors consider the patent system essential to the viability of private enterprise. In their March 14, 2000, announcement, President Clinton and Prime Minister Blair urged that "raw fundamental data on the human genome . . . should be made freely available to scientists everywhere."[29] A number of biotechnology companies lost a substantial percentage of their market capitalization as investors sold shares in record numbers. The chief concern of many sellers was that biotechnology patent rights would be weakened or subject to uncertainty.[30] The PTO responded by issuing a press release on March 16, 2000, explaining that U.S. patent policy was unaffected by

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[28] Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MANAGEMENT SCIENCE 173 (Feb. 1986).

[29] Peter G. Gosselin & Paul Jacobs, "Clinton, Blair to Back Access to Genetic Code," LOS ANGELES TIMES C1 (Mar. 14, 2000).

[30] Greg Heberlein, "Market movers: Biotech bubble pops as Nasdaq falls 200," THE SEATTLE TIMES C1 (Mar. 15, 2000).

the joint statement. As the impact of the Clinton-Blair announcement was better understood, the stock prices of many biotechnology enterprises rebounded.[31]

The *Eli Lilly* decision introduces legal uncertainties that will be keenly felt by those industries that most heavily rely upon the patent system. The broad language of the *Eli Lilly* opinion apparently may be read outside the double patenting context, further impacting the core patentability requirement of novelty.[32] Certainly the Federal Circuit's new standard of inherent anticipation departs dramatically from longstanding patentability requirements on which industry and the patent bar have long relied, and presents a distinct ground for granting *certiorari* in this case.

## III. The Federal Circuit's Decision Undermines the Basic Statutory Presumption of Validity of Issued Patents by Imposing Upon Innovators the Burden of Proving Their Patents Were Expeditiously Procured.

The Federal Circuit also announced a troublesome addition to the so-called "two-way" double patenting standard. Under the two-way double patenting standard, a later-issued patent is invalid only if the claims of each patent would have been obvious in view of the claims of

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[31] Bob Woods, "Biotech Stocks Rebound After Analysts Address Clinton Speech," NEWSBYTES NEWS NETWORK (Mar. 15, 2000).

[32] 35 U.S.C. § 102 (2000).

the other patent.[33] Because a species may be patentable over a genus,[34] use of two-way double patenting would appear to render the Stark patent (claiming a method of treating anxiety) patentable over the Molloy patent (claiming a serotonin blocking method).

The Court of Appeals never reached this analysis. Federal Circuit precedent establishes that a patentee obtains the benefit of the two-way double patenting doctrine only if the PTO is solely responsible for the delay in causing the second-filed application to issue prior to the first.[35] In this case, the court below concluded that delays in procurement of the Molloy patent were not solely the responsibility of the PTO.[36] The Federal Circuit's evidentiary basis for reaching this conclusion was quite limited, however. The court relied upon no more than the fact that Eli Lilly had filed several continuing applications while prosecuting the Molloy patent, as well as an expert's statement that claim 7 of the Molloy patent could have been procured earlier than it was. Among other issues, the court never considered the prosecution rate of the Stark patent, the difficulty of the issues surrounding the Molloy patent, as well as the pendency of other applications presented to the PTO during this period.

The Federal Circuit should have relied upon more than its intuition that the Molloy patent could have been

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[33] *In re Berg*, 140 F.3d 1428, 1437 (Fed. Cir. 1998).

[34] 251 F.3d at 975 (Newman, J., dissenting from denial of rehearing *en banc*).

[35] *In re Berg*, 140 F.3d at 1437.

[36] 251 F.3d at 969, n.7.

obtained more quickly. The accused infringers did not assert the laches defense in the trial court. Nor did the lower courts find that Eli Lilly had engaged in fraud or inequitable conduct before the PTO. Indeed, because the complete "prosecution history," or record of patent acquisition proceedings in the PTO, was not made of record in this litigation, the lower courts possessed no rigorous basis for evaluating whether the Molloy patent was timely procured or not.

The decision below also holds broader consequences. The Federal Circuit has now saddled patentees with both the burdens of production and persuasion of demonstrating that they solicited their patents with all possible speed. This ruling conflicts with the statutory provision that issued patents bear a presumption of validity.[37] It will also have deleterious consequences upon the administrative process of patent procurement. The complex legal and technological issues so commonplace in the patent law are not always amenable to the hasty resolution compelled by the Federal Circuit's decision.

Commentary in the popular press suggests that some innovators have abused the patent acquisition process by delaying the issuance of their patents.[38] However, the patent community is responding to such abuses through principled reform mechanisms. Statutory amendments

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[37] 35 U.S.C. § 282 (2000).

[38] *See, e.g.*, Charles Ornstein, *Law keeps generics in limbo: Drug makers deny abusing patent rules*, DALLAS MORNING NEWS 1A (June 24, 2001).

now found patent term based upon the application's filing date, rather than the issue date of the resulting patent.[39] As well, a nascent doctrine of prosecution laches is at work in the lower courts.[40] There was no need for the Court of Appeals effectively to impose an irrebutable presumption that a prosecution involved inappropriate delays simply because it was lengthy. This Federal Circuit holding too was in error, and it as well provides a distinct reason for this Court to grant *certiorari* in this case.

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[39] *See* 35 U.S.C. § 154 (2000).

[40] *See, e.g.*, David L. Marcus, *Is the Submarine Patent Torpedoed?:* Ford Motor Co. v. Lemelson *and the Revival of Continuation Application Laches*, 70 TEMPLE L. REV. 521 (1997).

## CONCLUSION

For the foregoing reasons, *amici curiae* respectfully request that this Court grant the Petition for Writ of Certiorari.

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Dated: December 11, 2001